510K SUMMARY FOR PUBLIC DISCLOSURE

K063759

AUG 15 2007

Applicant:

TEMPTIME Corporation
116 American Rd.
Morris Plains, NJ 07950

Contact:

Chris Caufield
Director, Sales and Sales Administration

Date Summary Prepared:

21 November 2006

Device Name:

HEATmarker™ Time Temperature Indicator

Common Name:

Time Temperature Indicator (TTI)

Classification Name:

Physical/Chemical Process Indicator

Equivalent Device:

SteriTec Dry Heat Indicator Labels

Device Description:

The HEATmarker™ TTI monitors the temperature history over time for any medical device to which it is affixed. The TTI can be used to monitor the heat exposure of devices at the unit package level. The TTI is constructed similar to a label that allows it to be permanently affixed to a medical device, or to the medical device packaging.

The visible surface of the TTI contains an area of color-changing ink surrounded by an area of fixed color. The TTI varies in color from start point (light) to end point (dark), defined as the time when the inner, active area reaches the same color as the fixed reference area. TTIs are categorized by the length of time at a specified temperature until end point is reached, for example, 3 months at 5°C.

Intended Use:

The HEATmarker™ Time-Temperature Indicator is intended to be used by a health care provider to distinguish between medical devices that have been or have not been exposed to a specific time and temperature profile of interest.

Technological Characteristics:

Both the HEATmarker™ TTI and the predicate device are manufactured utilizing inks that change color in response to exposure to a given temperature

for a specified time. The HEATmarker™ TTI uses a static reference color as a comparison to determine when end point is reached while the predicate device undergoes a color change from green to black.

Non-clinical Studies:

Emergency Medical personnel have used HEATmarker™ TTIs in a number of studies addressing the possibility of heat abuse to medical devices carried in emergency vehicles. The TTIs changed color in accordance with the Mean Kinetic Temperature recorded on the vehicles using electronic temperature recorders.

HEATmarker™ TTIs have been shown to react according to the Arrhenius relationship with regard to time and temperature. Studies of the polymerization of the substituted diacetylene monomers support this relationship as do more recent studies involving inks made from these monomers.

Conclusion:

The HEATmarker™ TTI changes color in a predictable manner when exposed to a given temperature for a specified period of time. As with the predicate device, this allows the TTI to demonstrate that the medical device to which it is affixed has been exposed to a quantity of heat characterized by a specified time-temperature profile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2007

Steve Feldman
Vice President, Quality and Regulatory Affairs
TEMPTIME Corporation
116 American Road
Morris Plains, New Jersey 07950

Re: K063759
Trade/Device Name: HEATmarker™ Time Temperature Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: OCI
Dated: June 7, 2007
Received: June 7, 2007

Dear Mr. Feldman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number:

K063759

Device Name:

HEATmarker™ Time Temperature Indicator

Indications for Use:

When affixed to a medical device by a health care provider (user), the HEATmarker™ Time-Temperature Indicator (TTI) is indicated, via a permanent color change, for the purpose of distinguishing between medical devices that have exceeded a selected time-temperature profile of interest to the user from devices that have not exceeded that profile.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K063759